April 4, 2007

The Honorable Andrew C. von Eschenbach
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

I am writing to express my strong concern that the Food and Drug Administration (FDA) has failed to investigate serious allegations of potentially dangerous levels of lead in some vitamin products.

On January 19, 2007, Consumerlab.com, an independent company that tests dietary supplements, issued a report about a number of multivitamins. One of the disturbing findings of this report was that one particular product — Vitamin Shoppe Multivitamins Especially for Women — was contaminated with lead. A daily dose of two pills contained 15.3 micrograms of lead. The results of this study were reported in major media outlets.[1]

The presence of such high levels of lead in these products presents a potential threat to the public health. It is undisputed that lead serves no useful purpose in the body and can have severe physiological effects on children and adults — including permanent neurological harm, reduced intelligence, hypertension, aggressive behavior, impaired brain function, organ failure, and death — even at very low levels.[2] Lead also poses serious reproductive risks: exposure to high levels of lead may increase the likelihood of miscarriages and stillbirth in pregnant women,

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[1] *A Vitamin a Day May Do More Harm Than Good*, MSNBC (Jan. 19, 2007) (online at www.msnbc.msn.com/id/16655168/).

[2] Agency for Toxic Substances and Disease Registry (ATSDR), *Case Studies in Environmental Medicine: Lead Toxicity: Physiological Effects* (online at www.atsdr.cdc.gov/HEC/CSEM/lead/physiologic_effects.html); Centers for Disease Control and Prevention (CDC), *Third National Report on Human Exposure to Environmental Chemicals*, 38-44 (July 2005) (online at www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf).

while lower levels of exposure can affect fetal and early childhood development.[3] Because the effects of lead can occur at very low levels and may be difficult to detect, public health experts agree that prevention is critical and urge the elimination of all exposures to lead.[4]

The amount of lead found in a daily dose of the Vitamin Shoppe Multivitamins for Women product — 15.3 micrograms — represents a potentially dangerous level. This amount might not be immediately toxic, but it could cause serious harm over time, particularly for a woman who is pregnant or breastfeeding or who may become pregnant. If accidentally taken by a child, this amount could be even more dangerous.

There is no uniform standard for permissible amounts of lead in food or dietary supplements. Instead, there are multiple relevant standards: (1) informal FDA guidelines for "tolerable levels" of daily dietary lead intake; (2) FDA guidance suggesting specific limits for lead in certain foods such as shellfish and candy; (3) a California law requiring a warning on any food or supplement containing lead above a certain amount; and (4) a widely accepted public health standard recognizing that all exposures to lead involve some level of risk and that, at least for children, there may be no safe level of exposure.

While FDA has not established a general limit on lead in foods and dietary supplements, the agency has suggested guidelines for the amount of lead that consumers can safely ingest through their diet and set specific limits on lead content in certain foods. The guidelines, FDA's "provisional total tolerable intake levels," provide the following limits on daily lead intake: for adults, 75 micrograms; for pregnant women, 25 micrograms; and for children age five and under, six micrograms.[5] In addition, the agency has suggested that shellfish should not contain more than 1.7 parts per million (ppm) of lead, and candy that is likely to be eaten often by small children should not contain more than 0.1 ppm of lead.[6] Notwithstanding these guidelines, FDA has noted that "some risk exists with any level of lead exposure" and has described its approach

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[3] *Id.*

[4] *Id.*; CDC, *Preventing Lead Poisoning in Young Children*, 1, 5, 8 (Aug. 2005) (online at www.cdc.gov/nceh/lead/publications/PrevLeadPoisoning.pdf).

[5] FDA, *Dangers of Lead Still Linger*, FDA Consumer (Jan.-Feb. 1998) (online at www.cfsan.fda.gov/~dms/fdalead.html); FDA, Center for Food Safety and Applied Nutrition, *Guidance for Industry: Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy* (Nov. 2006) (online at www.cfsan.fda.gov/~dms/pbguid2.html).

[6] FDA, Center for Food Safety and Applied Nutrition, *Guide for the Control of Molluscan Shellfish, Chapter II. Growing Areas: Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood* (2003) (online at www.cfsan.fda.gov/~ear/nss2-42d.html).

as a policy of "reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest levels that can be practicably obtained."[7]

The amount of lead in a daily dose of the Vitamin Shoppe product — 15.3 micrograms — is more than half of FDA's suggested "total tolerable level" for a pregnant woman (25 micrograms) and more than twice the suggested tolerable level for a small child (6 micrograms).[8] In terms of concentration, the vitamins contained 4.77 ppm of lead, nearly three times FDA's suggested limit for lead in shellfish and 47 times its limit for lead in candy likely to be frequently consumed by children.[9] In addition, these vitamins are not likely to be an individual's sole dietary source of lead. According to FDA, consumers ingest an average of 2.5 micrograms of lead every day from dietary sources.[10] Given this background exposure, the daily ingestion of over half of the "total tolerable intake level" from a single dietary source raises serious questions about the safety of that product.[11]

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[7] FDA, Center for Food Safety and Applied Nutrition, *Guidance for Industry: Lead in Candy Likely to be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy* (Nov. 2006) (online at www.cfsan.fda.gov/~dms/pbguid2.html).

[8] FDA, *Dangers of Lead Still Linger*, FDA Consumer (Jan.- Feb. 1998) (online at www.cfsan.fda.gov/~dms/fdalead.html). FDA has recognized that vitamin products not necessarily intended for children still may pose a risk to children. For example, in 1997, FDA issued regulations regarding iron-containing dietary supplements after a number of children were poisoned by such supplements, including prescription supplements intended for pregnant women. *See* FDA, *Preventing Iron Poisoning in Children* (Jan. 15, 1997) (online at www.cfsan.fda.gov/~dms/bgiron.html).

[9] Email from Dr. Tod Cooperman, President, Consumerlab.com, to Majority Staff, House Committee on Oversight and Government Reform (Mar. 16, 2007).

[10] FDA, *Dangers of Lead Still Linger*, FDA Consumer (Jan.- Feb. 1998) (online at www.cfsan.fda.gov/~dms/fdalead.html); CDC, *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention*, App. I (Mar. 2002) (online at www.cdc.gov/nceh/lead/CaseManagement/caseManage_appendixes.htm). See also CDC, *Third National Report on Human Exposure to Environmental Chemicals*, 38-44 (July 2005) (online at www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf).

[11] FDA, *Dangers of Lead Still Linger*, FDA Consumer (Jan.-Feb. 1998) (online at www.cfsan.fda.gov/~dms/fdalead.html); CDC, *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention*, App. I (Mar. 2002) (online at www.cdc.gov/nceh/lead/CaseManagement/caseManage_appendixes.htm). See also CDC, *Third National Report on Human Exposure to Environmental Chemicals*, 38-44 (July 2005) (online at www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf).

This amount of lead also exceeds the California standard.[12] Under California's law, a product must bear a warning label informing consumers of the risk of harm from lead poisoning whenever the exposure level of lead in the product exceeds 0.5 micrograms per day.[13] With 15.3 micrograms of lead per daily dose, the Vitamin Shoppe product exceeded this threshold by more than 30 times and should have carried a warning label.

Finally, under the public health protective standard agreed upon by the nation's experts in public health and toxicology — the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) — the level of lead in the Vitamin Shoppe product is a clear cause for concern. Both CDC and ATSDR have concluded that there is no known safe level of lead exposure.[14] These agencies note that the "levels at which health effects have been observed are constantly being revised as new data are generated, and for children, there may be no threshold for developmental effects."[15] Further, both CDC and ATSDR have stated that prevention is the only effective public health response to lead poisoning and consequently call for the elimination of all sources of lead exposure.[16]

Given the potential public health hazard posed by this product, I was disturbed to learn that your agency had taken no meaningful steps to investigate these allegations. In a briefing to my staff on March 15, 2007, FDA officials appeared to be unfamiliar with the details of the Consumberlab.com findings, even though FDA's own documents state that 15.3 micrograms of lead in a product taken daily is many times the daily amounts of lead to which adults are typically exposed through the environment and may pose serious health risks.[17]

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[12] California Health and Safety Code, Div 20, Chap. 6.6 s. 25249.6 Safe Drinking Water and Toxic Enforcement Act of 1986.

[13] Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, *Proposition 65 Safe Harbor Levels: No Significant Risk Levels for Carcinogens and Maximum Allowable Dose Levels for Chemicals Causing Reproductive Toxicity* (Aug. 2006).

[14] ATSDR, *Case Studies in Environmental Medicine: Lead Toxicity: Physiological Effects* (online at www.atsdr.cdc.gov/HEC/CSEM/lead/physiologic_effects.html); CDC, *Third National Report on Human Exposure to Environmental Chemicals*, 38-44 (July 2005) (online at www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf).

[15] *Id.*

[16] *Id.*; CDC, *Preventing Lead Poisoning in Young Children*, 1, 5, 8 (Aug. 2005) (online at www.cdc.gov/nceh/lead/publications/PrevLeadPoisoning.pdf).

[17] FDA, *Dangers of Lead Still Linger*, FDA Consumer (Jan.- Feb. 1998) (online at www.cfsan.fda.gov/~dms/fdalead.html).

At the briefing the FDA officials also stated that they had not seen the full report because Consumerlab.com would not give it to them for free. After the briefing, my staff contacted Consumerlab.com and learned that the complete report is available online for a fee of $10. My staff paid this fee and obtained immediate online access to the report, including details on Consumerlab.com's testing methods and findings.

It also appears that FDA has taken no steps to independently investigate the Vitamin Shoppe product and to determine whether there was contamination, whether any contamination was limited to that product, and, perhaps most important, the source of the contamination.

FDA's inaction is even more alarming given that these findings are far from isolated. In fact, the prevalence of lead in dietary supplements has been a serious issue for at least a decade. In 1997, several public health organizations petitioned FDA to set limits on the amount of lead allowed in calcium supplements and antacids, based on findings that many such supplements were contaminated with lead.[18] In 2003, a study showed toxic levels of lead in a different type of supplement, herbal medicine products (HMPs).[19] One in five of the HMPs tested contained heavy metals, and of those containing lead, the lead content ranged from five to 37,000 parts per million (ppm).[20] By comparison, the federal limit for lead in paint is 600 ppm. Paint is not intended for ingestion; vitamins are.

FDA has clear authority to act in this matter. A lead-contaminated supplement is adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) if it contains lead at a level that "may render the food injurious to health." Under the Act, this means that FDA has the authority to investigate and possibly take steps to eliminate this hazard.[21]

In this instance, Vitamin Shoppe has voluntarily removed this particular lead-tainted product from the shelves. However, unless the source of the contamination is determined, FDA cannot ensure that it will not recur, either in a Vitamin Shoppe product or in a product made by another manufacturer.

Please answer the following questions:

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[18] Natural Resources Defense Council, *Our Children at Risk: The 5 Worst Environmental Threats to their Health*, Ch. 3 (Nov. 1997) (online at www.nrdc.org/health/kids/ocar/ocarinx.asp).

[19] Robert B. Saper, et al., *Heavy Metal Content of Ayurvedic Herbal Medicine Products*, Journal of the American Medical Association, 1 (Dec. 15, 2004).

[20] *Id.*

[21] 21 U.S.C. §342.

(1) What steps has FDA taken in response to the Consumerlab.com findings of lead contamination in the Vitamin Shoppe women's multivitamin?

(2) What steps does FDA plan to take to address the issue of lead contamination in vitamins by any manufacturer?

(3) Does FDA need additional legal authority to respond to the Consumerlab.com findings? If so, what additional authority would be necessary for FDA to respond effectively?

(4) Does FDA need additional resources to respond to these findings? If so, what additional resources would be necessary for FDA to respond effectively?

Please respond to these questions no later than April 18, 2007.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Sarah Despres or Robin Appleberry at (202)225-5056.

Sincerely,

Henry A. Waxman (psb)

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member